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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,185	08/10/2000	John F. Gerber	GER-100XC1	6539
23557 7590 10/21/2003 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION 2421 N.W. 41ST STREET SUITE A-1 GAINESVILLE, FL 326066669			EXAMINER PATTEN, PATRICIA A	
			ART UNIT	PAPER NUMBER
			1654	
DATE MAILED: 10/21/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/636,185	GERBER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Patricia A Patten	1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The Amendment After final filed 8/8/2003 has been entered.

Upon further consideration, a new non-final rejection is in order.

Claims 1 and 9-11 are pending in the application and were examined on the merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to the 'chemical compound' which is a 'helper factor'; sufficient guidance with regard to exactly what compound the 'chemical compound' encompasses is not present in the Specification as filed. The term 'chemical compound' lacks Written Description because it is not clear that Applicants were actually in possession of, via isolation, of any 'chemical factor'. Applicants have not contemplated a structure or function of any 'chemical factor' and therefore the skilled artisan would not know how to reproduce such a factor.

Claims 1 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed

invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

As indicated *supra*, the Instant specification has not provided ample guidance to permit the skilled artisan to make the 'chemical compound' as Instantly claimed. No guidance is provided by which one would actually isolate or extract such a substance from the microorganism. Since microorganisms are known to produce numerous compounds, it would require a substantial inventive contribution from one of skill in the art to ascertain what the 'chemical compound', as recited in the Instant claims actually is, and how to produce it/extract it/isolate it.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 'has all the identifying characteristics of ATCC PTA-2324'. However, it is not clearly disclosed in the Instant specification what the 'identifying characteristics' are. Is this specifically deposited microorganism the microorganism which corresponds to Seq. ID. No. 1? This is not made perfectly clear within the Instant specification, and is deemed confusing because as stated by the Instant specification, nematodes are in association with many different types of microorganisms. One of ordinary skill in the art would not be able to ascertain what Applicants mean by 'identifying characteristics' based upon the Specification and thus this phrase is deemed indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Moriama et al. (JP 06165670A).

The phrase 'wherein said microorganism is found in association with nematodes' was given its broadest interpretation within reason. The Specification teaches that the microorganism is indigenous to the nematode, and is thereby released upon crushing the nematode body (p.6 Instant specification). Because Moriama et al. performed the same method via crushing the nematode body, and subsequently culturing the *P.penetrans* in this medium, it is deemed that Moriama et al. also released the 'microorganism' which was inherently indigenous to the nematode. Although Moriama et al. did not specifically mention that the microorganism which has been deposited as ATCC PTA-2324 was present in the culture, it is deemed that since Applicants teach that this microorganism is associated with nematodes, and because Moriama et al. cultured nematodes with *P.penetrans*, this microorganism must have been inherent to the culture medium. Further, although claim 1 states 'has all the identifying characteristics of', these characteristics are not known (please see rejection as set forth under 35 USC 112 Second paragraph supra). Moriama et al. did not specifically mention where the culture was mixed or antibiotics were added (claims 9 and 10) and therefore it is deemed that an antibiotic was not present, and that the culture was not mixed since Moriama et al. did not specifically disclose such information.

### ***Claim Rejections - 35 USC § 103***

-The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Moriama et al. (JP 06165670A) in view of ATTC (1992).

The teachings of Moriama et al. (JP 06165670A) were discussed supra. Moriama et al. did not specifically teach wherein lipids and or manganese sulfate were added to support the growth of *Pasteuria* endospores.

ATTC (1992) reported several media formulations which included magnesium sulfate as a nutritive addition for Bacterial growth (i.e., pp.478-479, formulations 1479, 1483, 1486, 1492).

One of ordinary skill in the art would have been motivated to have added magnesium sulfate into a culture medium for bacteria because addition of magnesium sulfate would have provided extra nutrition to facilitate the growth process of said bacteria. It was clear from the ATTC catalog that magnesium sulfate was a common additive into bacterial culture media. Thus, the ordinary artisan would have had a reasonable expectation that the addition of magnesium sulfate would have been an advantageous addition to a growing bacterial culture to ensure proper bacterial nutrition for growth.



Art Unit: 1654

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703) 308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

10/15/03

A handwritten signature in black ink, appearing to read 'Patricia Patten', with a large, stylized initial 'P'.

**PATRICIA PATTEN  
PATENT EXAMINER**